REMARKS

Claims 22-38 and 56, of which claim 22 is amended herein, appear in this application for the Examiner's review and consideration. Claim 22 has been amended to clarify the invention by reciting the non-adhesive liner of the printed patch as being " made of a material that is not permeable to the active or agents", support for which is found in paragraphs [0117], [0122], [0152], [0158] and [0189] of the published application. As no new matter is introduced, entry of the amendments at this time is respectfully requested. It is understood that process and system claims 40-48, 50, 53-55 and 57-79 have been withdrawn from consideration but will be rejoined when the printed patch of claim 22, from which they directly or indirectly depend, is allowed.

Claims 22-25 and 37 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent No. 5,958,447 to Haralambopoulos et al. (referred to hereafter as "Haralambopoulos") in view of U.S. Patent No. 6,335,030 to Hoeck et al. (referred hereafter as "Hoeck").

The Examiner is correct in stating that Haralambopoulos teaches an active substance in a powder form that is sprinkled, deposited or spread on an exposed adhesive surface of a patch. However, unlike in the present invention, the active substance in Haralambopoulos is not maintained on the exposed adhesive surface of the patch since it is then effectively driven by low heat or pressure into the adhesive matrix, where it becomes embedded at a depth just below the surface of the adhesive matrix as evidenced by the fact that the entire surface area of the adhesive matrix, previously powdered and non-tacky, regains its pressure sensitive adhesive properties (FIGs. 2 and 3, and col. 7 lines 20-25 of Haralambopoulos). Thus, Haralambopoulos does not teach the non-adhesive liner that is claimed in the present application.

Hoeck does not remedy the deficiencies of Haralambopoulos. Hoeck discloses four types of transdermal patches, namely the reservoir type, the matrix-type, the drug-in-adhesive type and the multi-laminate type. However, Hoeck only provides examples of the reservoir type, the drug-in-adhesive type and multi-laminate type patches. No example is provided for a matrix-type patch. Thus, there is no enabling disclosure in Hoeck for a matrix-type transdermal patch.

Moreover, in the matrix-type patch of Hoeck, the active substance is placed within a non-adhesive polymeric material, typically hydrogel or soft polymer (col. 4 lines 37-39 of Hoeck). Thus, the combination of Hoeck and Haralambopoulos would result in a structure having no

exposed active substance on the surface of the patch. In contrast, in the printed patch of the present invention, the active substance is placed on a non-adhesive polymeric material where it remains because the non-adhesive liner is made of a material that is not permeable to the active agent or agents.

In the Declaration under 37 C.F.R. § 1.132 filed with the U.S. Patent and Trademark Office on February 26, 2007 in connection to the present patent application, Dr. Stern stated that transdermal delivery of high molecular weight molecules such as polypeptides or proteins is hampered if these molecules are incorporated into adhesive or any cross-linked matrix (see Section No.8 of the Declaration). Dr. Stern further stated that incorporating high molecular weight molecules into an adhesive or any cross-linked matrix results in incomplete and low release of the molecules which depend upon their molecular weight and the pore size inside the matrix. Dr. Stern also provided an example of growth hormone incorporated within Vigilon, a non-adherent hydrogel sheet consisting of cross-linked polyethylene oxide and water, and indicated that the release of the hormone from the cross-linked matrix was always incomplete (see Section No.8 of the Declaration).

It is to be noted that the structure of the patch of the present invention enables achieving a desired dose of a drug in a short period of time with high bioavailability (paragraphs [0026] and [0027] of the published application and Section No. 10 of the Declaration). Thus, the patch of the present invention, wherein the dried pharmaceutical composition is placed upon the non-adhesive liner, has distinct features compared to those of the patch disclosed by Hoeck, wherein the active agent is embedded within the non-adhesive polymeric material. Thus, even if Haralambopoulos is combined with Hoeck, one of ordinary skill in the art would not obtain the printed patch of the present invention which comprises a non-adhesive liner and a dried pharmaceutical composition present upon the non-adhesive liner. To further distinguish the printed patch of the present invention from the patch of Hoeck, claim 1 has been amended to recite "wherein the non-adhesive liner is made of a material that is not permeable to the active agent or agents". Thus, this rejection should be withdrawn.

Claim 38 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos in view of Hoeck. As explained above, the patch disclosed by Haralambopoulos in view of Hoeck is distinct from the printed patch of the present invention.

Therefore, the printed patch recited in claim 38 wherein the pharmaceutical composition further comprises at least one component selected from an anti-oxidant, a buffering agent and a preservative is not obvious over Haralambopoulos in view of Hoeck. Therefore, the rejection over Haralambopoulos in view of Hoeck should be withdrawn.

Claim 56 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos in view of Hoeck. As explained above, Haralambopoulos teaches powdered patches wherein an active substance in a powder form becomes incorporated or embedded in the adhesive matrix of a transdermal patch by application of heat and/or pressure. Even though Hoeck discloses an iontophoretic patch in which an electrical potential gradient is used for transferring the drug, incorporating electrodes in a patch for iontophoresis requires the drug to be in a solution. However, Haralambopoulos teaches powdered patches wherein the active agent is in a powder form. Thus, there is no motivation to integrate electrodes into the patch of Haralambopoulos in view of Hoeck because no electrical potential gradient would be generated to transfer the powdered drug of Haralambopoulos. Therefore, the rejection should be withdrawn.

Claims 26, 28-29, 32-33 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos in view of Hoeck in view of U.S. patent No. 6,274,166 to Sintov et al. (referred to hereafter as "Sintov"). As explained above, combination of Haralambopoulos and Hoeck does not teach or suggested the printed patch of the present invention. Sintov does not remedy their deficiencies.

Sintov teaches proteins that can be incorporated into adhesive patches but all the examples disclosed by Sintov relate to topical application of insulin in solution on the skin of animals. Thus, it would not be obvious to one of ordinary skill in the art at the time the invention was made to formulate a dried pharmaceutical composition comprising a large molecule such as insulin into a printed patch of the present invention. Furthermore, since Sintov does not remedy the deficiencies of Haralambopoulos and Hoeck, even if Sintov is combined with Haralambopoulos and Hoeck, one of ordinary skill in the art would not obtain the presently claimed invention. Therefore, the rejection over the cited references should be withdrawn.

Claims 27, 29, 32-34 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos in view of Hoeck in view of US 6,274,582 to Marin (referred to hereafter

as "Marin").

As explained above, the combination of Haralambopoulos and Hoeck does not teach or suggested the printed patch of the present invention. Marin does not remedy their deficiencies.

Marin teaches the use of hGH in combination with a cortisol synthesis inhibitor for preventing or treating conditions related to Metabolic Syndrome. Though Marin teaches that the active agents or compositions may be formulated as transdermal patches (col. 5 lines 37-41) and the administration may be transdermally (col. 5 lines 48-49), hGH was administered by subcutaneous or intramuscular injection in solution in all the examples of Marin (col. 3 lines 56-57 and col. 6 lines 9-13). Thus, it would not be obvious to one of ordinary skill in the art at the time the invention was made to formulate a dried pharmaceutical composition comprising a large molecule such as hGH onto a printed patch for transdermal delivery. Furthermore, since Marin does not remedy the deficiencies of Haralambopoulos and Hoeck, even if Marin is combined with Haralambopoulos and Hoeck, one of ordinary skill in the art would not obtain the presently claimed invention. Therefore, the rejection over the cited references should be withdrawn.

Claims 22-26, 29-36 and 38 were provisionally rejected for nonstatutory obviousness-type double patenting over claims 12, 18-19 of copending application 11/327,016. It is noted that the provision has not occurred in that application. Applicant agree to file a terminal disclaimer in this or the copending application, whichever is found to be allowable at a later time than the other, to avoid any possible obviousness type double patenting issues. Thus, the nonstatutory obviousness-type double patenting rejection should be withdrawn.

In view of the above, it is believed that the entire application is in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a telephonic or personal interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the claims.

Respectfully submitted,

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